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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/449,096      | 11/24/1999  | BERNARD ACKERMAN     | ACKRAD-5            | 5859             |

7590 12/31/2002

Arthur L Plevy Esq  
Duane Morris & Heckscher LLP  
100 College Road West Suite 100  
Princeton, NJ 08540

EXAMINER

SERKE, CATHERINE

ART UNIT PAPER NUMBER

3763

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

# Office Action Summary

Application No.

09/449,096

Applicant(s)

ACKERMAN, BERNARD

Examiner

Catherine Serke

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7,9 and 11-23 is/are pending in the application.
- 4a) Of the above claim(s) 17-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9,11-16,22 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

### **DETAILED ACTION**

Examiner thanks applicant for correctly listing the pending and withdrawn claims. This office action includes the corrections.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 rejected under 35 U.S.C. 103(a) as being unpatentable over Valtchev.

Valtchev discloses a single channel balloon uterine injector that includes a catheter body with a balloon on the distal end for injection of dye or contrast medium into a uterine cavity. Figure 7 clearly shows an embodiment that includes a lumen extending through the body of the catheter tube with openings at or adjacent the distal end (external openings) for communication with the interior of the uterus. Furthermore, inside the lumen is a reduced diameter portion for restricting fluid flow out of the lumen and for creating a back pressure to force into through the opening into the balloon (second opening).

At the time of the invention it would have been obvious to reposition the reduced diameter portion inside the lumen into any position along the lumen distal to the opening into the balloon (second opening) and proximal to the openings adjacent the distal end (external openings). Furthermore, the reduced diameter portion could be incorporated immediately adjacent to or integral with the external openings and still provide the same function (i.e.

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restricting fluid flow and creating a back pressure to force fluid through the opening into the balloon). Any individual skilled in the art of fluid dynamics would recognize this fluid flow property. Positioning the flow restrictor (26' see figure 7 in Valtchev) integral with the external openings of Valtchev would be a design modification consistent with the teachings of Valtchev and would not alter the function or performance of the device. The motivation for this alternative design choice can be found in Valtchev column 3 lines 24-31 which states "[o]bviously, many modifications and variations of the present invention are possible...the invention may be practiced otherwise than as specifically described".

Claims 1-16 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ackerman in view of Valtchev.

Ackerman discloses a catheter with a tubular body having two lumens with openings respectively. A polyurethane balloon is disposed on the distal end of the device and is in communication with one lumen opening. The second lumen and opening communicate with the exterior of the device to dispense a diagnostic fluid into the uterus. The body of the catheter is flexible and has a moveable sheath disposed thereon. As shown in figures 4A and 4B the balloon can be inflated into first and second predetermined shapes.

Ackerman meets the claim limitations as described above but fails to disclose a lumen having an external opening generating backflow within the lumen for communication with the uterus and a second opening for communication with the interior of the balloon.

Valtchev discloses a single channel balloon uterine injector that includes a catheter body with a balloon on the distal end for injection of dye or contrast medium into a uterine cavity. Figure 7 clearly shows an embodiment that includes a lumen extending through the body of the

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catheter tube with openings at or adjacent the distal end for communication with the interior of the uterus. Furthermore, inside the lumen is a reduced diameter portion for restricting fluid flow out of the lumen and for creating a back pressure to force into through the opening into the balloon.

At the time of the invention, it would have been obvious to incorporate the teachings of Valtchev regarding the single lumen for inflation and injection into the invention of Ackerman. The two references being for insertion and injection into the uterus are analogous in the art and therefore a combination is proper. Additionally, motivation for the combination can be found in the disclosure of Valtchev (see 1:60+). The Valtchev device is specifically designed to provide a uterine injector that is simpler to use. By incorporating the single lumen into the invention of Ackerman, the combined device eliminates the need to have the medical technician manipulate both an inflation syringe and another medical device.

Regarding claims 1, 9, 22-23, Ackerman in view of Valtchev meet the claim limitations but fail to specifically disclose the external openings generating a back flow or a reduced diameter external opening. At the time of the invention it would have been obvious to reposition the reduced diameter portion of Valtchev inside the lumen into any position along the lumen distal to the opening into the balloon (second opening) and proximal to the openings adjacent the distal end (external openings). Furthermore, the reduced diameter portion could be incorporated immediately adjacent to or integral with the external openings and still provide the same function (i.e. restricting fluid flow and creating a back pressure to force fluid through the opening into the balloon). Any individual skilled in the art of fluid dynamics would recognize this fluid flow property and that positioning the flow restrictor (26' see figure 7 in Valtchev) integral with the external openings of Valtchev would be a design modification consistent with the teachings of

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Valtchev and would not alter the function or performance of the device. The motivation for this alternative design choice can be found in Valtchev column 3 lines 24-31 which states “[o]bviusly, many modifications and variations of the present invention are possible...the invention may be practiced otherwise than as specifically described”.

***Response to Arguments***

Applicant's arguments with respect to claims 1-7,9,11-16 and 22-23 have been considered but are moot in view of the new ground(s) of rejection.


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine Serke whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine Serke *CS*,  
December 23, 2002

  
BRIAN L. CASLER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700